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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/646,111 | 11/20/2000 | Christopher Marriott | REF/MARIOTT/ | 3979 |
| 7590 | 04/29/2004 | | EXAMINER | |
| Bacon & Thomas Fourth Floor 625 Slaters Lane Alexandria, VA 22314-1176 | | | TRAN, SUSAN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 09 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on 09 April 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. Applicant's reply has overcome the following rejection(s): 112, second paragraph.
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 50 and 51.

Claim(s) rejected: 42-49 and 52.

Claim(s) withdrawn from consideration: _____.

8. The drawing correction filed on _____ is a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. Other: _____.

Attachment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. US 4,725,387, in view of Trofast et al. WO 95/05805 and Douglas et al. US 5,635,200.

Hirao teaches a process of shaping crystals of sugar alcohols by obtaining a saccharified starch solution with high maltose content, allowing crystallization, and separating the crystallized solid (column 2, lines 38 through column 3, lines 1-11). The viscosity of the solution can be regulated by the addition of water-soluble organic solvent, or elevated temperature (column 4, lines 45-68; and example 1). Hirao does not teach the viscosity of less than 25 Pas at a shear rate of 1s^{-1} . However, no criticality is seen in the particular viscosity since Hirao obtains the same result desired by the applicant, e.g., a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape (column 7, lines 33-53). Accordingly, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable viscosity of the solution to obtain the claimed invention.

Hirao does not teach the solid crystals can be used for inhalation. However, Hirao in column 5, lines 20-58 teaches besides anhydrous crystals of maltitol, *other sugar alcohols such as sorbitol, maltotriitol and maltotetraitol* can be used for various uses, e.g., for foods, cosmetics, and *drugs*. Hirao further teaches that maltitol or crystalline mixture solid can be prepared into desirable shape, including granule with a granulator (column 7, lines 66 through column 8, lines 1-4).

Trofast teaches a stable crystallinic form of fine-grained substance or substance mixture useful for inhalation (page 4, lines 23-30). The substance includes salbutamol sulfate, ipratropium bromide, or salmeterol xinafoate (page 7, lines 26 through page 8, lines 1-3). The substance may be combined with carriers suitable for inhalation, such as lactose, maltose, maltitol, starch, and its hydrates (page 6, lines 21-31). Thus, it would have been obvious for one of ordinary skill in the art to optimize the solid crystalline mixture of Hirao as a carrier useful for inhalation of pharmaceutical formulation in view of the teachings of Trofast, because the references teach the advantageous result in the use of carrier, such as maltitol and lactose monohydrate as a carrier for inhalation formulation.

Hirao and Trofast are relied upon for the reasons stated above. The references are silent as to the teaching of carbomer in an aqueous solution. However, carbomer is a well known starch or thickener, or binder in pharmaceutical art. Douglas teaches an oral administration composition comprising starch or carbopol as an aqueous solution thickener (column 7, lines 22-32). Hence, it would have been obvious for one of

ordinary skill in the art to modify Hirao's starch solution using carbopol taught by Douglas. The unexpected result is free flowing crystal having desire size and shape.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al., in view of Staniforth WO 96/23485.

Hirao is relied upon for the reasons stated above. Hirao does not teach the size range of the crystallized solid.

Staniforth teaches carrier particles useful in dry powder inhalers comprising one or more crystalline sugars including lactose, having particles diameter between from 60 μm to 180 μm (page 10, lines 2-17). Thus, it would have been obvious for one of ordinary skill in this art to modify Hirao crystalline solid carrier to have the particle size suitable for inhalation in view of the teachings of Staniforth, because the references teach the advantageous result in the use of crystalline sugars in pharmaceutical art. The unexpected result is a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape.

Response to Arguments

Applicant's arguments filed 04/09/04 have been fully considered but they are not persuasive.

Applicant points out that the Final Office Action includes claims that were no longer present in the application. The examiner apologizes for the inconvenience it may cause. The rejected claims in the final office action were inadvertently misnumbered. Appropriate corrections have been done.

Applicant argues that the cited references do not teach the crystal prepared according to the presently claimed invention have significantly higher mean elongation ratio and surface smoothness. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., significantly higher mean elongation ratio and surface smoothness) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To place the application in condition, it was suggested to incorporate the limitation of claim 50 into the generic claim 42.

Claims Allowable

Claims 50 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0606. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY EXAMINER
TECHNICIAN
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